DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 10 2004

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Kathleen M. Sanzo
Morgan, Lewis & Bockius LLP
1111 Pennsylvania Avenue, N.W.
Washington, D.C. 20004

Re: Docket No. 2004P-0231/CP1 & SUP1

Dear Ms. Sanzo:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated May 13, 2004, and related supplement dated August 4, 2004, both submitted on behalf of Pfizer Inc. Your petition requests that FDA deny approval of New Drug Application (NDA) 21-426 for Omnitrop (somatropin [rDNA origin] for injection), submitted by Biochemie U.S., Inc., and Sandoz, Inc., under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act. Specifically, your petition contends that:

(1) It is scientifically and legally improper for FDA to rely on, reference, or otherwise use the clinical and manufacturing information establishing the safety and effectiveness of Pfizer's Genotropin (somatropin [rDNA origin] for injection) to approve Omnitrop, and

(2) The Omnitrop data do not adequately address the safety, effectiveness, and manufacturing considerations for recombinant human growth hormone products or the specific product differences between Genotropin and Omnitrop.

FDA has been unable to reach a decision on your petition because it raises significant and complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

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